Libby - toxicity assessment


1260894 - R8 SDMS

Re: Combine Cancer and Non-Cancer Assessments
Kevin Teichman to: Carol Campbell 04/28/2011 03:33 PM
Cc: Becki Clark, Carol Rushin, Deborah McKean

Thanks. Valid points. Even if we keep as two documents, I would hope they would read like they're harmonized. Mayl would be less than the additional time it would take to conduct interagency review and/or respond to the interagency co

Deb, Becki: Thoughts?

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Carol Campbell	Carol R is on vacation until Saturday. I think the...	04/28/2011 05:21:53 PM

From: Carol Campbell/R8/USEPA/US
To: Kevin Teichman/DC/USEPA/US@EPA
Cc: Becki Clark/DC/USEPA/US@EPA, Carol Rushin/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA
Date: 04/28/2011 05:21 PM
Subject: Re: Combine Cancer and Non-Cancer Assessments

Carol R is on vacation until Saturday. I think there are a couple of downsides- 1) Rfc may run into snags at OMB, 2) IUR might have different issues with groups that think is incorrect due to it not being more stringent than the present IRIS value, and 3) extra time it might take to combine two documents.

Call me on my cell 303-519-9825 if you want to talk today. Otherwise I will be in on Friday. cc

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Kevin Teichman	Carol: I truly hate to add to people's stress as th...	04/28/2011 02:34:21 PM

To: Kevin Teichman/DC/USEPA/US,
Cc: Becki Clark/DC/USEPA/US@EPA, Carol Rushin/R8/USEPA/US@EPA, CN=Deborah McKean/OU=R8/O=USEPA/C=US@EPA,
Bcc:
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Carol:

I truly hate to add to people's stress as they prepare for the upcoming meetings in Libby, but I need to raise a related issue that has been elevated to me.

My staff prepared the following summary of the recent intra-Agency meeting, which highlights the comments about combining the two Libby amphibole assessments (cancer and non-cancer) into one. From this summary, it seems to me that this would be a wise thing to do to facilitate interagency review.

I'm not asking for R8 folks to do this work, especially at this time (although I would certainly welcome such assistance and would want R8 folks to review the resulting document).

Please advise.

Thanks.

Kevin

[attachment "IRIS_Libby Amphibole Asbestos_Agency Review comments on combining.docx" deleted by Carol Campbell/R8/USEPA/US]

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Excerpts from the Agency Review comments on Libby Amphibole Asbestos pertaining to combining the noncancer and cancer assessments into one document

Written comments were received on both documents from OCHP, OSWER, Region 2, Region 8, and the Technical Review Working (TRW) Group Asbestos Committee (workgroup made up of Regions 1-10, ERT, OPPT, ORD, OSWER, ATSDR). Additionally, Regions 7 and 10 commented on the cancer assessment. All comments below are related to combining the documents; note the highlighted text for specific recommendations.

NONCANCER ASSESSMENT

OCHP

It is my strong preference that the cancer and non-cancer documents be combined. There are a number of places in the noncancer document that are inconsistent with the cancer document, in particular the sections on toxicokinetics, mode of action and susceptible populations and lifestages. The concept of a harmonized document is supported by the following:

Bogdanffy MS, Daston G, Faustman EM, Kimmel CA, Kimmel GL, Seed J, Vu V (2001). Harmonization of cancer and noncancer risk assessment: proceedings of a consensus-building workshop. *Toxicol Sci* 61(1):18-31.

National Research Council (1994). Science and Judgment in Risk Assessment. National Academy Press: Washington, DC.

National Research Council (2009). Science and Decisions: Advancing Risk Assessment. National Academy Press: Washington, DC.

U.S. EPA (2002). A Review of the Reference Dose and Reference Concentration Processes. Risk Assessment Forum, Washington, DC, EPA/630/P-02/002F.

U.S. EPA (1997). Summary of the U.S. EPA Colloquia on a Framework for Human Health Risk Assessment (Volume 1, 1997). Risk Assessment Forum, Washington, DC, EPA/600/R-99/001.

U.S. EPA (1998). Summary of the U.S. EPA Colloquium on a Framework for Human Health Risk Assessment (Volume 2, 1998). U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC.

U.S. EPA (2006). A Framework for Assessing Health Risks of Environmental Exposures to Children. National Center for Environmental Assessment, Washington, DC, EPA/600/R-05/093F.

OSWER

In our recent review of the cancer assessment for Libby Amphibole we recommended merging the two documents. This remains a recommendation for this document as well. However, we acknowledge that might have the undesirable effect of delaying slightly the noncancer assessment, which we feel is essentially ready for external

review, because the cancer assessment is not in our opinion ready for that step (primarily because of the mesothelioma modeling seems inappropriate –see our earlier comments).

However, combing these two documents would force consistency where it is needed, and in particular necessitate a discussion about why the non-cancer assessment appears to indicate that Libby Amphibole may be more potent than other forms of asbestos, but the cancer assessment suggests the opposite. It is of course possible that Libby Amphibole has the potential to produce unacceptable risk for non-cancer effects at a lower concentration that it would for cancer but this is contrary to predominant theory of asbestos toxicity. Some discussion of this point is warranted.

When the document is merged with the draft cancer assessment report, particular attention should be made to presenting and discussing any relevant exposure pathways or scenarios, including comparing and contrasting what has changed from previous assessment studies.

Region 2

Overall the document is well written and easy to follow. It is suggested that the document be included in the cancer risk assessment for Libby Amphibole Asbestos for completeness. If this is not possible, then it is important to in the IRIS file to link both documents in such a way that the user of the information is aware of the existence of both documents.

Region 8

A second theme running throughout these comments is the scarcity of information provided in a number of the sections, relative to the abundance of information provided in the Libby IUR Toxicological Review. It is not clear whether or not the RfC document will be integrated into the overall IUR document. If so, many of our concerns regarding incompleteness of information may be diminished. However, if the RfC document is to be a standalone document, then it may be useful to expand a number of the sections with information from the IUR document.

Page 13, Section 4.1.2.1: This summary of previous studies appears to be overly truncated and insufficient. We would prefer the analogous section in the IUR document. In Sentence 5, why is "Federal Agencies" capitalized? Insert a comma after "1967".
Pages 32 and 33, Mode of Action Section: As written, this section is incomplete. The discussion of physical-chemical attributes of mineral fibers associated with toxicity is meager; no citations are provided. The pathophysiology discussion is meager and again, no citations are provided. It is not clear whether this RfC document will be combined with the IUR document. If not, the mode of action section in the IUR document would be most informative here.

Page 34, Section 4.4: Section 4.4 appears to be incomplete. The analogous section in the IUR document would be informative here.

CANCER ASSESSMENT

OSWER

Recommend including the cancer and non-cancer assessments in the same document.

We strongly suggest that these two components of the assessment be combined into one document to avoid redundancy in future document development/review activities. If cancer and non-cancer remain in separate documents it would be important that both documents are IRIS documents to ensure they have equal consideration in risk assessments. However, if the document remains focused on the carcinogenic hazard and to derive an inhalation unit risk (IUR) for LA, then there are potential several sections of the document on health effects other than cancer that could be removed.

Region 10

Overall, this document presents a vast amount of information on research related to the health effects posed by Libby Amphibole. In some cases, I think some of the information included does not contribute significantly to understanding health effects from Libby Amphibole and could be removed to streamline the document. I also assume that once a noncancer potentcy value (e.g., reference concentration) for Libby Amphibole is developed, additional text will be added to this review document.

TRW

It is suggested that NCEA consider pairing external peer review of this document with the RfC document that is in development so that they can be evaluated at the same time (see major concern #2 below).

Second, the Asbestos Committee is concerned that the potency value is lower than expected and doesn't appear to be consistent with health effects observed in Libby. Is it possible that the noncancer health effects are masking the cancer outcomes? Could it be that people in Libby are dying of noncancer disease before the cancers associated with asbestos exposures manifest? If this document included both cancer and noncancer potency values, then perhaps this question would be addressed.